REMARKS

The present response is intended to be fully responsive to all points of objection and/or rejection raised by the Examiner and is believed to place the application in condition for allowance. Favorable reconsideration and allowance of the application is respectfully requested.

Status of Claims

Claims 1, 3, 4, and 6-10 are pending in the application. Claims 1, 3, 4, and 6-10 have been rejected. Claims 1, 3, and 4 have been amended.

CLAIM REJECTIONS UNDER 35 U.S.C. § 103

In the Office Action dated October 19, 2006, the Examiner rejected claims 1, 3, 4, and 6-10 under 35 U.S.C. § 103(a), as being allegedly unpatentable over Mao. The Examiner alleged that Mao disclosed: (a) biodegradable medical implant devices that incorporate 1-65% active agent; (b) that any antipsychotic drugs (e.g. clozapine, haloperidol, and risperidone) can be used; and (c) use of lactic acid copolymers. The Examiner alleged that "The difference... between Mao and the instant claims is [only] the amount of the haloperidol" (October 19, 2006 Office Action page 3, first full paragraph). Therefore, Examiner alleged that it would have been obvious to modify the implant of Mao to arrive at the implants claimed in the subject claims.

In a Response dated March 8, 2007, Applicants pointed out to the Examiner that (a) the polymers of Mao differ from those of the present invention in that the polymers of Mao contain a phosphate ester linkage, which is not present in either polylactide or lactide-co-glycolide copolymers; and (b) the phosphate ester materially changes the basic characteristics of thereof, e.g. the degradation pattern and ability to incorporate an active compound into the polymers.

In an Advisory Action dated April 17, 2007, the Examiner alleged that the claim language "consisting essentially of" does not exclude the device of Mao because the device of Mao "is biodegradable, non-toxic and releases antipsychotic drug, haloperidol, when

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present." Further, the Examiner alleged that "the claimed invention does not specifically claim or un-claim modified or unmodified lactide or glycolide"; and the subject specification does not make clear what Applicants regard as constituting a material change in the basic and novel characteristics of the invention.

In response, in order to expedite prosecution and without agreeing to the correctness of the rejection, amended claim 1 is directed to a surgically implantable drug delivery system comprising a biodegradable polymer or copolymer ***consisting essentially of*** polylactide or lactide-co-glycolide copolymer and 20 to 40% haloperidol fabricated into an individual, surgically implantable implant via solvent casting and compression molding at a temperature and pressure which allows the haloperidol-polymer material to flow into a mold for the individual, surgically implantable implant which is surgically implanted underneath the skin of a patient, delivers steady state concentrations of haloperidol to the patient for 5 months or more and is removable from the patient in the event the patient exhibits unwanted side effects following implantation. Amended claim 4 is directed to a method of producing an individual, surgically implantable implant which is surgically implanted underneath the skin of a patient for delivery of steady state concentrations of haloperidol to the patient for 5 months or more comprising: (a) dissolving haloperidol and a biodegradable polymer ***consisting essentially of*** polylactide or lactide-co-glycolide copolymer in acetone; (b) solvent casting the haloperidol and biodegradable polymer solution to produce a completely dry haloperidol-polymer material; and (c) molding under compression the dry haloperidol-polymer material at a temperature and pressure which allows the haloperidol-polymer material to flow into a mold for the individual, surgically implantable implant which is surgically implanted underneath the skin of a patient, delivers steady state concentrations of haloperidol to the patient for 5 months or more, and is removable following implantation into a patient in the event the patient exhibits unwanted side effects following implantation.

By contrast, the polymer in the implants of Mao does not consist essentially of polylactide or lactide-co-glycolide copolymer. Rather, as described in more detail hereinbelow, (a) the polymer of Mao contains phosphate ester linkages; and (b) the presence of phosphate ester linkages in the polymer of Mao alters materially the basic and novel characteristics of the invention; namely, the release rate of the implants.

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The subject specification shows that release rate of the implants constitutes a basic characteristic of the claimed implants

The subject specification states:

> "The surgically implantable preparations of the present invention are designed to last for months to years" (subject specification page 7, lines 33-34).
>
> "Haloperidol released from the bioerodible implant of the present invention maintains its bioactivity and is delivered at steady state concentrations to the patients for periods of five months or more" (page 13, lines 11-15).

Thus, the subject specification clearly shows that Applicants consider release rate of the implants to constitute a basic characteristic of the claimed implants. In view of this teaching of the subject specification, the basic characteristics of polymer of Mao are materially altered from the claimed implants of the subject invention. Accordingly, the polymer of Mao is excluded by the phrase "consisting essentially of polylactide or lactide-co-glycolide copolymer" in the subject claims.

For the sake of completeness, Applicants now reproduce the evidence that (a) the polymers of Mao differ from those of the present invention in that the polymers of Mao contain a rhombate ester linkage, which is not present in either polylactide or lactide co-

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